IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 7328
Bradford J. DUFT et al.	Art Unit: 1645
Appl. No.: 08/870,762	Examiner: Sarvamangala J.N. DEVI
Filed: June 6, 1997	Atty. Docket: 226/104 US
For: METHODS FOR TREATING OBESITY	

Brief on Appeal

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants (herein, "Appellants") hereby appeal under 37 C.F.R. § 41.37 the Final Rejection of Claims 1-7 and 9-17 in the above-identified application (Final Office Action, mailed February 11, 2008; Advisory Action, mailed April 30, 2008). This Appeal Brief follows a Notice of Appeal filed May 12, 2008, and is accompanied by a petition for extension of time under 37 C.F.R. § 1.136 and fee under 37 C.F.R. § 1.17 for one-month. The Commissioner is hereby authorized to charge payment for any requisite fee set forth for this Appeal Brief to Applicants' Deposit Account No. 010535 referencing Atty. Dkt. No. 226/104 US.

CERTIFICATE OF TRANSMITTAL UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being electronically filed via EFS-Web at the United States Patent and Trademark Office, on the date shown below.

Debra A. Villanueva
Name of Person Filing Paper

7 August, 2008
Date of Deposit

Signature of Person Filing Paper

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Real Party of Interest

The real party of interest is Amylin Pharmaceuticals, Inc. a Delaware corporation with offices at 9360 Towne Centre Drive, San Diego, California 92121.

Related Appeals and Interferences

An appeal is pending in related U.S. Appl. No. 09/445,517, filed December 6, 1999, which application is a national stage filing under 35 U.S.C. § 371 of PCT/US98/11753, filed June 5, 1998, and which application is a continuation-in-part of the instant application.

Status of Claims

Claims 1-7 and 9-17 are pending and under appeal. Claim 8 was previously canceled.

Status of Amendments

All amendments in the instant application have been entered. In particular, the after-final amendment filed April 11, 2008, in response to the Final Office Action mailed February 11, 2008, has been entered.

Summary of Claimed Subject Matter

Independent Claims 1, 7, 14 and 16 relate to methods of treating obesity. As described in the specification, it has been surprisingly discovered that amylin as well as amylin agonists can be used for treatment of obesity in humans. See, *e.g.*, specification page 9, lines 2-5. Unless indicated differently, reference to "specification" herein refers to the substitution specification submitted September 29, 2005 (already of record).

1. Independent Claim 1

Independent Claim 1 is directed to a method of treating obesity in a human subject consisting of administering to the subject a composition comprising an amylin or an amylin agonist and a pharmaceutically acceptable carrier in an amount effective to inhibit weight gain or induce weight loss, and wherein the subject is in need of treatment for obesity, support for which may be found in the specification at e.g. page 9, lines 6-16; page 21, lines 3-10.

2. Dependent Claim 2

Claim 2, dependent on Claim 1, is directed to amylin agonist analogues, support for which may be found in the specification at, e.g., page 9, lines 24-26.

3. Dependent Claim 3

Claim 3, dependent on Claim 2, is directed to pramlintide (^{25,28,29}Pro-h-amylin) (SEQ ID NO:1), support for which may be found in the specification at, e.g., page 13, lines 11-12.

4. Dependent Claim 4

Claim 4, dependent on Claim 1, is directed to subcutaneous administration of the composition of Claim 1, support for which may be found in the specification at, e.g., page 21, line 4.

5. Dependent Claim 5

Claim 5, dependent on Claim 4, is directed to administration of the composition of Claim 4 from 1 to 4 times per day, support for which may be found in the specification at, e.g., page 23, lines 16-18.

6. Dependent Claim 6

Claim 6, dependent on Claim 5, is directed to dosages of the administered composition containing amylin or amylin agonist (30 μg/dose to 300 μg/dose), support for which may be found in the specification at, e.g., page 23, lines 13-18.

7. Independent Claim 7

Independent Claim 7 is directed to a method of treating obesity in a human subject comprising administering to the subject an amount effective to inhibit weight gain or induce weight loss of a composition comprising an obesity relief agent consisting of an amylin or an amylin agonist and a pharmaceutically acceptable carrier, wherein the amount is effective to treat obesity in the subject, and wherein the subject is in need of treatment for obesity, support for which may be found in the specification at e.g. page 9, lines 6-16; page 21, lines 3-10.

8. Dependent Claim 9

Claim 9, dependent on any of Claims 1-3, is directed to QID administration of the composition containing the amylin or amylin agonist at 30 μg/dose, support for which may be found in the specification at, e.g., page 24, line 5.

9. Dependent Claim 10

Claim 10, dependent on any of Claims 1-3, is directed to TID or QID administration of a composition containing 60 μg/dose amylin or amylin agonist, support for which may be found in

the specification at, e.g., page 24, lines 5-6.

10. Dependent Claim 11

Claim 11, dependent on Claim 1, is directed to specific dosages (about 0.01 to about 5 mg/day) of amylin or amylin agonist in the composition of Claim 1, support for which may be found in the specification at, e.g., page 23, line 6.

11. Dependent Claim 12

Claim 12, dependent on Claim 1, is directed to specific dosages (about 0.05 to about 2 mg/day) of amylin or amylin agonist in the composition of Claim 1, support for which may be found in the specification at, e.g., page 23, line 6-7.

12. Dependent Claim 13

Claim 13, dependent on Claim 1, is directed to specific dosages (about 0.1 to about 1 mg/day) of amylin or amylin agonist in the composition of Claim 1, support for which may be found in the specification at, e.g., page 23, line 7.

13. Independent Claim 14

Independent Claim 14 is directed to a method of treating obesity in a human subject comprising administering to the subject a compound selected from the group consisting of an amylin, an amylin agonist, and salts thereof, wherein the compound is administered in an amount effective to treat obesity in the subject by inhibiting weight gain or inducing weight loss, wherein the subject is in need of treatment for obesity, and wherein the compound is not administered in conjunction with another obesity relief agent, support for which may be found in the specification at e.g. page 9, lines 6-16; page 21, lines 3-10.

14. Dependent Claim 15

Claim 15, dependent on any of Claims 1-3, further defines the invention by requiring that the weight of the human subject is reduced after four weeks of treatment relative to the weight prior to treatment, support for which may be found in the specification at e.g. page 24, lines 15-17.

15. Independent Claim 16

Independent Claim 16 is directed to a method of treating obesity in a human subject comprising administering to the subject an amount effective to inhibit weight gain or induce

weight loss in the subject of a composition consisting essentially of an amylin or an amylin agonist, wherein the amount is effective to treat obesity by inhibiting weight gain or inducing weight loss in the subject, and wherein the subject is in need of treatment for obesity, support for which may be found in the specification at e.g. page 9, lines 6-16; page 21, lines 3-10.

16. Dependent Claim 17

Claim 17, dependent on any of Claims 7, 14 and 16, is directed to pramlintide (^{25,28,29}Pro-h-amylin) (SEQ ID NO:1), support for which may be found in the specification at, e.g., page 13, lines 11-12.

Grounds of Rejection to be Reviewed on Appeal

1. Whether claims 7, 14, 16 and 17 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 34 and 35 of Gaeta *et al.* (U.S. Patent No. 5,686,411) (hereinafter "Gaeta," already of record) as evidenced by Tsanev (*Vutr. Boles* **23**:12-17, 1984, hereinafter "Tsanev," already of record).

2. Whether claims 7, 14 and 16 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 11 and 13 of Beaumont et al. (U.S. Patent No. 5,321,008) (hereinafter "Beaumont," already of record) as evidenced by Tsanev and Rink *et al.* (U.S. Patent No. 5,739,106) (hereinafter "Rink," already of record).

3. Whether claims 1, 7, 14 and 16 and claims 2-6, 9-13, 15 and 17 dependent therefrom are unpatentable under 35 U.S.C. § 112, first paragraph, as containing new matter.

4. Whether claims 1-7 and 9-17 are unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope of the claims.

5. Whether claims 1-7, 9-14, 16 and 17 are unpatentable under 35 U.S.C. § 102(a) as being anticipated by Kolterman et al. (WO 96/40220) (hereinafter "Kolterman '220," already of record) as evidenced by Tsanev.

6. Whether claims 7, 14 and 16 are unpatentable under 35 U.S.C. § 102(e)(2) as being anticipated by Beaumont as evidenced by Tsanev.

7. Whether claims 7, 14, 16 and 17 are unpatentable under 35 U.S.C. § 102(e)(2) as being anticipated by Gaeta as evidenced by Tsanev.

8. Whether claims 1-7, 9, 11-14, 16 and 17 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Kolterman et al. (*Diabetologia* 39:492-499, April 1996)

(hereinafter "Kolterman 1996," already of record) as evidenced by Itasaka *et al.* (*Psychiatr. Clin. Neurosci.* 54:340-341, June 2000) (hereinafter "Itasaka," already of record).

Argument

1. Claims 7, 14, 16 and 17 are not obvious under the judicially created doctrine of obviousness-type double patenting over Gaeta as evidenced by Tsanev.

The rejection of Claims 7, 14, 16 and 17 (Final Office Action, page 7, item 26) under the judicially created doctrine of obviousness-type double patenting over claims 34 and 35 of Gaeta as evidenced by Tsanev is in error for reasons of record and reasons provided herewith.

Initially, the current rejection (Rejection 1), and the following rejection (Rejection 2), are obviousness-type double patenting rejections. The predecessor court to the Federal Circuit has held that

> [t]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown. (*In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-57 (C.C.P.A 1977) (quoting *In re Spormann*, 363 F.2d 444, 448, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966))).

Accordingly, all Examiner arguments invoking inherency of the alleged evidence (e.g., Tsanev and/or Rink) in Rejections 1-2 are properly viewed consistent with *In re Shetty*, wherein the alleged specific property must be known in order to be deemed inherent.

Claims 7, 14, 16 and 17 are not obvious

The alleged prior art does not include all of the elements of the instant claims as required by the law. In particular, the references provide no guidance concerning the identification of or intent to treat a subject in need of treatment for obesity. Accordingly, the instant claims are patentably distinct over the reference claims.

Specifically, Claims 7, 14, 16 and 17 are directed to methods for treating obesity in a human subject in need of such treatment, which methods require administration of a composition or compound containing an amylin or an amylin agonist, wherein the amount of the composition or compound administered is effective to treat obesity by inhibiting weight gain or inducing weight loss, and wherein the subject is in need of treatment for obesity.

In contrast, as acknowledged by the Examiner (Final Office Action, page 7, lines 7-9), claims 34 and 35 of Gaeta are merely directed to methods for the treatment of diabetes mellitus

in a mammal comprising the administration of a therapeutically effective amount of a particular amylin agonist analogue. That is, Gaeta is silent with respect to the treatment of obesity.

In an attempt to cure the deficiency of Claims 34 and 35 of Gaeta, the Examiner relies on Tsanev to assert that 80-90% of diabetic patients are obese. In view of the disclosure of Tsanev, the Examiner asserts (Final Office Action, page 7, lines 23-25) that "[g]iven the art-known prevalence of intrinsic obesity in 80% to 90% of diabetic patients as disclosed by Tsanev, at least one of the human diabetic patients used in the method disclosed in the '411 patent qualified as a human patient in need of treatment for obesity."

The Examiner further asserts (Final Office Action, page 7, lines 26-28) that "the method of the '411 patent comprising or consisting of the administration of 0.1 to 5 mg, or 0.5 to 1.0 mg of the amylin agonist, ^{25,28,29}Pro-human amylin alone or in conjunction with insulin or glucagon, to a diabetic human anticipates the instant claims (*emphasis added*)."

Even in view of Tsanev, a claim to treating diabetes mellitus with an amylin agonist analogue (i.e., claims of Gaeta) does not teach or suggest treating subjects as currently claimed. More particularly, nothing in the cited claims teaches or suggests the identification of or intent to treat a subject in need of treatment for obesity. The courts have held that the phrase "in need thereof" (e.g., as recited in independent Claims 7, 14 and 16) is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003). Thus, since the cited claims do not teach or suggest treating obesity, the intent to treat human subjects in need of treatment for obesity, or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims. In this regard, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR,* 127 S.Ct. at 1741 (quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added). Indeed, the prior art must still suggest a predictable outcome to establish a *prima facie* case of obviousness. See, *e.g.*, *Takeda Chemical Industries, Ltd v. Alphapharm Pty., Ltd.* 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007).

The disclosure of Gaeta, whether evidenced by Tsanev or not, is silent with respect to the treatment of obesity. In particular, Gaeta did not disclose that an amylin or amylin agonist is useful for treating obesity in a human in need of treatment thereof. The Examiner's reliance on

inherency in the context of anticipation in the rejection(s) is contrary to the law. Indeed, anticipation based on inherency is appropriate only when the prior art relied upon necessarily includes all of the elements of the claims in question and is the natural result of following the instructions or examples of the prior art. See, *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 78 USPQ2d 1417, 1424 (Fed. Cir. 2006); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334, 74 USPQ2d 1398, 1407 (Fed. Cir. 2005) (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F. 3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003)). The Court in *Schering* relied in part on the decision *In re Cruciferous Sprouts Litigation,* 301 F.3d 1343, 1351, 64 USPQ2d 1202, 1206 (Fed. Cir. 2002) wherein it was noted that to demonstrate inherency, it was necessary to show that the prior art necessarily, always functions in accordance with the claims addressed. The requirement that the teaching of a reference always, under any circumstances, necessarily satisfies the recitation of the claims to make out a case of inherent anticipation was reaffirmed by the Federal Circuit in *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006). It is well settled that a determination of inherency cannot be established by probabilities or possibilities, but that it is incumbent upon the Examiner to establish the inevitability of the inherency which is propounded. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 635-36, 190 USPQ 59, 63-64 (CCPA 1976).

However, as acknowledged by the Examiner (Final Office Action, page 7, line 23), Tsanev discloses that 80-90% of diabetic patients are obese, which 80-90% falls short of the 100% (i.e., always, under any circumstances) criterion required by the present claims and required by the law. Accordingly, Claims 34 and 35 of Gaeta support neither *prima facie* obviousness nor anticipation with regard to the claimed invention.

The Examiner improperly asserts (Advisory Action, page 6, lines 5-16) that the prior method necessarily includes all of the elements of the instant claims as evidenced by Thompson *et al.* (*Diabetes* **46**: Suppl. 1, page 30A, 0116, 02 May 1997) (hereinafter "Thompson 1997," already of record). Appellants had filed a declaration under 37 C.F.R. §1.131 in the Response to Office Action filed December 2, 2002, which demonstrates that the current application antedates Thompson 1997 and was inventors' own work. Acknowledgment of Appellants declaration was provided by the Examiner in the Non-final Office Action dated June 1, 2006. Accordingly, Thompson 1997 is unavailable as prior art against the current application. More particularly,

Thompson 1997 cannot be used as evidence of an alleged inherency because the present invention antedates Thompson 1997. See *In re Shetty* (*Id.*)

Thus, the Examiner has failed to provide evidence or argument with any rational underpinning that the current claims are obvious in view of Gaeta as evidenced by Tsanev. Whatever else is taught by Gaeta and Tsanev, the references do not teach or suggest a method of treating obesity in a subject in need of treatment thereof. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the obviousness-type double patenting rejection.

2. Claims 7, 14 and 16 are not obvious under the judicially created doctrine of obviousness-type double patenting over Beaumont as evidenced by Tsanev and Rink.

The rejection of claims 7, 14 and 16 (Final Office Action, page 8, item 27) under the judicially created doctrine of obviousness-type double patenting over claims 11 and 13 of Beaumont, as allegedly evidenced by Tsanev and Rink, is in error for reasons of record and for the following reasons.

Claims 7, 14 and 16 are not obvious

Arguments relating to inherency in anticipation and obviousness analyses provided for Rejection 1 are hereby reiterated. Beaumont as evidenced by Tsanev and Rink does not include all of the elements required by the rejected claims. In particular, the references provide no guidance concerning the identification of or intent to treat a subject in need of treatment for obesity. Furthermore, the Examiner's reliance on argument based on alleged inherency in the Tsanev and Rink disclosures is legally deficient because the current rejection is for obviousness-type double patenting and is not an anticipation rejection. Accordingly, for at least this reason the instant claims are patentably distinct over the reference claims.

The subject matter of claims 7, 14 and 16 is discussed above . In contrast, Claim 11 of Beaumont is directed to a method for the treatment of diabetes mellitus in an insulin-requiring mammal (human) comprising administering a therapeutically effective amount of a calcitonin. Claim 13 of Beaumont is directed to a method of treatment of type II diabetes mellitus comprising the step of administering a therapeutically effective amount of an insulin and a calcitonin in an amount effective to achieve improved glycemic control over insulin therapy alone. However, the cited claims of Beaumont are silent with regard to treating obesity. Indeed,

Beaumont *per se* is silent with respect with treating obesity, reducing weight, or the effect of amylin or amylin agonist thereon.

The Tsanev disclosure has been discussed in the argument to the previous Rejection 1. The Rink disclosure merely contemplates amylin-induced appetite suppression in rodents. Indeed, the Rink patent does not describe the treatment of obesity in humans using amylin or amylin agonist, or intention to treat a human subject in need of treatment, as required by the claims of the present invention.

In view of the similarity of the current rejection to the rejection over Gaeta discussed above (Rejection 1), arguments provided above relating to nonstatutory obviousness-type double patenting with respect to Gaeta are reiterated. Even *arguendo* if Tsanev is read for the inherency it allegedly teaches, similar to the rejection over Gaeta, the Examiner's attempts to cure the deficiencies of Beaumont by citing the alleged prevalence of intrinsic obesity (80-90% according to Tsanev) falls short of the 100% required by the claims and required by the law in an anticipation rejection, and also falls short because Beaumont, whether evidenced by Tsanev and Rink or not, is silent with respect to the treatment of obesity and the identification of a subject population in need of treatment for obesity. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the obviousness-type double patenting rejection.

3. Claims 1, 7, 14 and 16 and claims dependent therefrom do not contain new matter under 35 U.S.C. § 112, first paragraph: new matter.

The rejection of Claims 1, 7, 14 and 16 and dependent claims 2-6, 9-13, 15 and 17 under 35 U.S.C. §112, first paragraph (Final Office Action, page 9, item 28), as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter rejection), is in error for the reasons of record and the following reasons. Because the rejection of Claims 1 and 14 contain additional elements of rejection beyond those cited for Claims 7 and 16, and because the Examiner has provide no express reason for rejections of Claims 2-6, 9-13, 15 and 17 in the current rejection, Appellants request that the following claim groupings be reviewed independently in order to forestall rejection of the dependent claims were they to stand or fall with independent Claims 1, 7, 14 and 16: a) Claim 1; b) Claims 2-6; c) Claims 7 and 16; d) Claims 9-13; e) Claim 14; f) Claim 15; and

g) Claim 17.

Claim 1 contains no new matter

To the extent that the rejection of Claims 7 and 16 have also been applied to Claim 1, arguments in favor of Claims 7 and 16 provided below are reiterated for Claim 1. Additionally, for Claim 1 the Examiner alleges (Final Office Action, page 10, line 22 to page 11, line 16) that the specification does not provide descriptive support for the transitional term of art "consisting" found in Claim 1 as amended. The term "consisting" as used in Claim 1 is a term of art (transitional claim language) that need not be specifically recited in the specification. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claims 2-6 contain no new matter

Arguments in favor of Claim 1, from which Claims 2-6 depend, are hereby reiterated. Because the Examiner has provided no express rejection of Claims 2-6, the rejection of Claims 2-6 is moot. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claims 7 and 16 contain no new matter

The Examiner alleges that the amendments to Claims 1, 7 and 16 which include the requirement of an amount "effective to inhibit weight gain or induce weight loss ... said subject is in need of treatment of obesity" (Final Office Action, page 9, last paragraph), or the grammatically equivalent phrasing of Claim 14, is not supported by the specification.

Support for the concept of inhibiting weight gain or inducing weight loss may be found in the specification at, e.g., page 9, lines 9-16, which discloses

> In one aspect, the invention is directed to a method of treating obesity in a human subject comprising administering to said subject an effective amount of an amylin or such an amylin agonist. By "treating or preventing" is meant the management and care of a patient for the purpose of combating the disease, condition or disorder, and includes the administration of an amylin or an amylin agonist to prevent the onset of symptoms or complications, alleviating the symptoms or complications, or eliminating the disease condition or disorder. Treating or preventing obesity therefor includes the inhibition of weight gain and inducing weight loss in patients in need thereof (*emphasis added*).

Further support for the amount of amylin or amylin agonist contemplated in the claims

may be found, e.g., at specification page 22, last two lines: "[t]herapeutically effective amounts of an amylin or amylin agonist, such as an amylin agonist analogue, for use in the control of obesity are those that decrease body weight." Accordingly, the alleged new matter asserted by the Examiner is not new matter and is fully supported by the specification.

The Examiner further alleges (Final Office Action, page 9, line last to page 10, line 3) that "[a]s claimed currently, 'an amount effective to inhibit weight gain or induce weight loss in said human subject' is not the amount of the recited amylin or the amylin agonist, but of the composition that 'comprises' an amylin, amylin agonist, or an amylin agonist analogue plus a pharmaceutically acceptable carrier plus any other element that is comprised with the composition." The amount effective to treat obesity of a composition comprising the required amylin or amylin agonist of the invention is determined by routine methods of pharmaceutical research, and that effectiveness is due to the amylin or amylin agonist in the composition administered to the human subject in need of treatment for obesity.

The Examiner further alleges (Final Office Action, page 10, line 22 to page 11, line 16) that the specification does not provide descriptive support for the transitional term of art "consisting" found in Claim 1 as amended. The term "consisting" as used in Claim 1 is a term of art (transitional claim language) that need not be specifically recited in the specification. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claims 9-13 contain no new matter

Arguments in favor of Claims 1-3, from which Claims 9-13 ultimately depend, are hereby reiterated. Because the Examiner has provided no express rejection of Claims 9-13 in the present rejection, the rejection of Claims 9-13 is moot. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claim 14 contains no new matter

To the extent that the rejection of Claims 1, 7 and 16 have also been applied to Claim 14, arguments in favor of Claims 1, 7 and 16 above are reiterated for Claim 14. Additionally, the Examiner further alleges (Final Office Action, page 10, lines 17-18) a lack of support for "an amount of a salt of amylin or an amylin agonist compound and its administration to a human subject in need of treatment for obesity wherein the amount of the salt compound is effective to

treat obesity in said subject by inhibiting weight gain or inducing weight loss, wherein the salt compound is not administered in conjunction with another obesity relief agent, as claimed currently in the amendment claim 14." Support for the concept of salts of the compounds of the invention in a broad sense for compounds useful in the invention may be found throughout the specification at, e.g., page 20, lines 20-21. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claim 15 contains no new matter

Arguments in favor of Claims 1-3, from which Claim 15 depends, are hereby reiterated. Because the Examiner has provided no express rejection of Claim 15 in the present rejection, the rejection of Claim 15 is moot. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Claim 17 contains no new matter

Arguments in favor of Claims 7, 14 and 16, from which Claim 17 depends, are hereby reiterated. Because the Examiner has provided no express rejection of Claim 17 in the present rejection, the rejection of Claim 17 is moot. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

4. Claims 1-7 and 9-17 are enabled under 35 U.S.C. § 112, first paragraph: enablement.

The rejection of Claims 1-7 and 9-17 under 35 U.S.C. §112, first paragraph (Final Office Action, page 11, item 29), as allegedly not enabling any person skilled in the art to use the invention commensurate in scope with the claims, is in error for the reasons of record and the following reasons. Appellants request that a) Claims 1-2, 4-7, and 9-16, and b) Claims 3 and 17 be reviewed independently.

The proper standard for determining compliance with the enablement requirement is whether the specification provides sufficient information to permit one skilled in the art to make and use the claimed invention. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The test of enablement is not whether experimentation is necessary, but rather whether any experimentation that is necessary is undue. A considerable amount of experimentation is permitted, provided that it is merely routine, or provided that the specification provides a reasonable amount of guidance with respect to the direction in which the

experimentation should proceed. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A specification that discloses how to make and use a claimed invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented "must be taken as in compliance with the enabling requirement of the first paragraph of $ 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (quoting *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (*emphasis in original*)).

Claims 1-2, 4-7 and 9-16 are enabled

An analysis of the Wands factors (*In re Wands, Id.*) for the rejected claims follows:

Regarding the quantity of experimentation needed, the standard for determining enablement is whether the experimentation needed to practice the invention is undue or unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). In this respect, one of ordinary in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation in view of the specification. Methods of synthesis of a defined group of compositions useful in the claimed methods are provided or known in the art, as are methods of administration and methods of weight determination.

Regarding the amount of direction or guidance presented, the specification broadly discloses that the claimed amylin or amylin agonist compounds are useful in the treatment of obesity in a subject in need thereof. There is express guidance as to modes of administration, therapeutic dosages, mechanisms for assessing therapeutic efficacy, as well as a working example to demonstrate the statistically significant ability of an exemplary amylin compound to treat obesity in a human subject in need thereof. In the working example, the human subjects were Type 2 diabetics. That the working example illustrated Type 2 diabetic subjects taking insulin does not render the scope of enablement limited to this subject population. Rather, it demonstrates that in a particularly difficult to treat, obese subject population (Type 2 diabetic subjects taking insulin), an exemplary amylin compound is therapeutically effective in the treatment of obesity.

Moreover, taken together with the teachings of the specification (e.g., page 18, para.3 to page 23, para. 2), the working example provides a base-line approach for establishing therapeutic efficacy of exemplary amylin compounds within the context of the presently claimed methods. Utilizing similar study structures, Appellants have in fact established that exemplary amylin

compounds are effective in the treatment of obesity in non-diabetic subjects as well (see, e.g., IDS entries AZ1, AZ2, AZ4 and AZ5 of Aronne, et *al.* *and* Smith, et *al.* of record). This evidence confirms the teachings of the specification, and demonstrates that Appellants' working example in fact provides enablement of the efficacy of a particularly difficult to treat, chronically obese subject population.

In yet another aspect, the Examiner also asserts that the specification does not enable administration by *any* route, or administration of "an amount effective to treat obesity" commensurate in scope with the claims. The Examiner is impermissibly attempting to limit the scope of enablement to the scope of the working examples. Based on the extensive guidance provided in the specification, including the human clinical study results, as well as the high level of skill in the art, the skilled artisan would be able to evaluate efficacy of amylin compounds in accordance with the methods of the inventions to ascertain therapeutically effective amounts of the recited amylin compounds. In fact, the Examiner's characterization of Example 1 only serves to underscore the enablement of the claims in this regard. For instance, Example 1 describes a clinical study wherein routine dosages were evaluated in human clinical subjects to ascertain a therapeutically effective dose as well as effective administration regimens.

With respect to reasons for doubting the objective truth of the specification, the Examiner asserts (Final Office Action, page 17, line 22 to page 18, line 3) that Appellants' prior discussion (Applicants' Appeal Brief filed July 2000) regarding Rink allegedly provides a reason for doubting the objective truth contained within the specification. When read in context, it is clear that Rink only contemplates amylin-induced appetite suppression in rodents, not in humans. Indeed, Rink does not describe the treatment of obesity in humans using amylin or an amylin agonist as required by the claims of the present invention. Accordingly, the Examiner's reliance on Applicants' Appeal Brief filed July 2000 regarding Rink (Final Office Action, page 17, lines 24-25) takes the disclosure of Rink out of context, which disclosure provided no evidentiary support for use of amylin or amylin agonist in humans for modulation of food intake.

Regarding the presence of absence of working examples, the working examples, in combination with the disclosure of the specification and knowledge of one skilled in the art, amply enable the full scope of the invention as presently claimed.

Regarding the nature of the invention, Appellants agree with the Examiner's assertion (Final Office Action, page 12, lines 23-26) that the nature of the invention is pertinent to the

treatment of obesity in a human subject in need of such treatment comprising or consisting of administering an amylin, an amylin agonist, or an amylin agonist analogue composition or compound in an amount effective to inhibit weight gain or induce weight loss in the subject. Specifically, the invention contemplates the treatment of obesity in human subject in need of treatment by the administration of an amylin or amylin agonist. Indeed, Appellants discovered that amylin or agonists thereof can be used for the treatment of obesity.

Regarding the state of the prior art, Appellants agree in part with the Examiner's characterization (Final Office Action, page 12, lines 27-29) of obesity or adiposity as a 'chronic disease' that is highly prevalent in modern society which is strongly associated with multiple conditions including diabetes mellitus, insulin resistance, hypertension, etc. However, the Examiner appears to have failed to note that the prior art does not disclose the subject matter of the claims of the present application taken as a whole. Indeed, it was Appellants' discovery that amylin or amylin agonists could be administered to a human subject in need of treatment for obesity. In this respect, one of ordinary skill in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation. Indeed, amylin compounds recited in the claims are generally recognized as a defined class of compounds, and the specification provides ample direction and guidance to those skilled in the art with regard to the identification of such amylin compounds useful in the context of the claimed methods.

Regarding the relative skills of those in the art, the relative skill of one or ordinary skill in the art to which the invention pertains is very high.

Regarding the predictability of unpredictability of the art, the Examiner alleges that the state of the art with regard to the use of amylin is unpredictable. In this regard, the Examiner asserts (Final Office Action, page 16, line 28 to page 17, line 14) that Baron *et al.* and Ratner *et al.* indicate the impracticability of using amylin as a therapeutic agent. Appellants disagree. Whether native human amylin is suitable for use as a commercial drug product is not a proper standard for judging the enablement of the present claims. Moreover, contrary to the Examiner's characterization of the cited references, it is submitted that both Baron *et al.* and Ratner *et al.* actually support enablement of the claimed invention. That is, given the teachings of the instant specification, one of ordinary in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation. This further

confirms that both amylin and amylin agonists are well known compounds that have been widely characterized. Given this, one of ordinary skill in the art would have the requisite skill to practice the invention commensurate in scope with the claims without undue experimentation.

Regarding the breadth of the claims, in rejecting the claims the Examiner has impermissibly attempted (e.g., Final Office Action page 11, line 27 to page 12, line 4) to limit the invention to the scope of the examples. Such a standard is legally incorrect. As set forth in MPEP 3 2164.02, "[f]or a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation." This is exactly what Appellants have provided. For example, Tables I - I1 and Examples 1-8 disclose data relating to the claimed methods and exemplary amylin compounds. Alone, this disclosure is sufficient such that one of ordinary skill in the art at the time the invention was made would have the ability to practice the invention commensurate in scope with the claims.

The Examiner further comments on the scope of the claimed amylin compounds, and asserts (Final Office Action, page 20, lines 4-5) that "the only amylin agonist analogue species within the recited broad genus that is being used for inducing weight loss in humans is pramlintide." Appellants disagree. Again, the Examiner appears to be focusing on Example 1 rather than the teachings of the specification as a whole and the level of ordinary skill in the art. In this regard, it is noted that amylin compounds recited in the claims are generally recognized as a defined class of compounds, and the specification provides ample direction and guidance to those skilled in the art with regard to the identification of such amylin compounds useful in the context of the claimed methods. Furthermore, the specification is replete with examples of amylin agonists, including functional variants, fragments, and derivatives of amylin and amylin agonists. See, e.g., specification page 13 para. 4 to page 17, para. 1. For example, given at least the discussion in the background concerning amylin agonists, as well as the description of SEQ ID NO: 12-17, one of ordinary skill in the art having read the specification would have the ability to select known amylin agonists without undue experimentation. Moreover, to the extent that any additional experimentation may be required, the performance of routine and well known steps cannot create undue experimentation even if it is laborious. See *In re Wands* (*Id.*); *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

Given the knowledge in the art, and based on the guidance provided in the specification regarding the extensive exemplary embodiments of amylin compounds, receptor binding assays and other assays for determining amylin activity, including the soleus muscle assay, and exemplary clinical study designs, additional therapeutically active amylin agonists can be identified within the context of the present claims without the need for undue experimentation. The specification provides numerous examples of compounds within the scope of the recited genus, and guidance with regard to assays and clinical studies in the examples useful to evaluate the efficacy of the compounds in the methods of the present invention. Based on such guidance, one of skill in the art would be able to practice the claimed invention with only routine experimentation.

Claim 2 requires that the amylin agonist of Claim 1 is an amylin agonist analogue. As generally understood by those of skill in the art, amylin analogues are compounds that are structurally related to the reference compound, i.e., amylin. As explained in the specification and understood by those having ordinary skill in the art, an amylin analogue can have one or more amino acid substitutions, deletions, inversions, or additions compared to a native or naturally occurring amylin. Furthermore, Claim 2 merely requires that the amylin analogue is an amylin agonist analogue. Thus, in accordance with the claims and the knowledge of those of ordinary skill in the art, the recited amylin agonist analogues are both structurally and functionally defined. Hence, Claim 2 is enabled.

The Examiner makes numerous comments with regard to the scope of various claim terms and transitional phrases. For instance, various claim terms such as obesity and administering are discussed in a broad context. While Appellants do not necessarily agree with the exact definition provided by the Examiner, Appellants do acknowledge the broad scope of such terms commensurate with the present specification. Furthermore, the Examiner comments on the claims use of traditional transitional phrases such as "comprising," "consisting of," and consisting essentially of'. In this regard, such language ha been used in the traditional context. Thus, within the context of the claimed methods for treating obesity, such terms of art would have their traditional meanings and limitations with regard to claim elements relevant to the treatment of obesity. However, such traditional claim terms would have no bearing on components, steps, or elements outside of the claimed scope of the treatment of obesity.

Accordingly, for at least these reasons the claims are enabled under 35 U.S.C. 3 112, first paragraph, and Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection of Claims 1-2, 4-7 and 9-16.

Claims 3 and 17 are enabled

To the extent that the rejection of Claims 1-2, 4-7 and 9-16 has been applied to Claims 3 and 17, arguments in favor of Claims 1-2, 4-7 and 9-16 are reiterated for Claims 3 and 17. Additionally, as acknowledged by the Examiner (Final Office Action, page 20, lines 4-5), pramlintide is described in the specification for inducing weight loss in human. Accordingly, there can be no question that use of pramlintide is enabled by the specification. Furthermore, because use of pramlintide is the sole claim element of Claims 3 and 17, there can be no question that Claims 3 and 17 are enabled. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection of Claims 3 and 17.

5. Claims 1-7, 9-14, 16 and 17 are not anticipated under 35 U.S.C. § 102(a) over Kolterman '220 as evidenced by Tsanev.

The rejection of Claims 1-7, 9-14, 16 and 17 under 35 U.S.C. §102(a), (Final Office Action, page 21, item 33), for alleged anticipation by Kolterman '220 as evidenced by Tsanev, is in error for the reasons of record and the following reasons.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also, MPEP §2131. The identical invention must be shown in complete detail as it is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989).

Claims 1-7, 9-14, 16 and 17 are not anticipated by the references

Claims 1-7, 9-14, 16 and 17 are directed *inter alia* to methods of treating obesity in a human subject in need of such treatment through administration of an amylin or an amylin agonist. In contrast, as acknowledged by the Examiner (Final Office Action, page 21, lines 19-23), Kolterman '220 merely describes the use of an amylin agonist (i.e., pramlintide) for treating type II diabetes mellitus. Indeed, Kolterman '220 merely demonstrates that administration of an amylin agonist significantly reduces postprandial plasma glucose concentrations in patients with type II diabetes mellitus. In particular, Kolterman '220 does not teach the use of an amylin or an amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients

administered an amylin or an amylin agonist. Indeed, Kolterman '220 is silent with regard to the effect of an amylin or an amylin agonist on body weight.

The Examiner further asserts (Final Office Action, page 21, line 30 to page 22, line 2) that "Kolterman et al. ('220) taught the benefit of obtaining weight loss in Type II diabetic patients by teaching that hyperglycemia associated with Type II diabetes can be reversed or ameliorated by weight loss sufficient to restore the sensitivity of the peripheral tissues to insulin..." A careful reading of Kolterman '220 at page 7, first paragraph, discloses that "the hyperglycemia associated with Type II diabetes can sometimes be reserved or ameliorated by diet or weight loss... (*emphasis added*)." Nevertheless, with respect to the use of amylin or amylin agonists for treatment of obesity in a subject in need thereof, Kolterman '220 is silent. Accordingly, whether or not Kolterman '220 discloses that weight loss is beneficial is irrelevant, at least because the Examiner has failed to state a nexus between administration of an amylin or agonist thereof and treatment for obesity.

In an attempt to cure the deficiency in Kolterman '220, the Examiner relies on Tsanev to allegedly provide evidence that 80-90% of diabetic patients are obese. The crux of the Examiner's argument appears to be (Final Office Action, page 22, lines 12-18) that "[g]iven Tsanev's express disclosure that 80 to 90% of type II diabetic patients are intrinsically obese, and given Kolterman's ('220) recognition that obesity is an intrinsic characteristic of most patients with Type II diabetes mellitus and the indication that these patients are in need of weight loss, Kolterman's ('220) method of subcutaneous administration of pramlintide to at least one Type II diabetic patient in an amount that falls within the range recited in the instant claims, necessarily serves as the claimed method of treating obesity and therefore anticipates the instantly claimed method (*emphasis added*)."

However, the 80-90% of obese diabetic patients alleged by Tsanev falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law as discussed in the response to the rejection under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 34 and 35 of Gaeta (Final Office Action, page 7, item 26) discussed above for Rejections 1-2. See e.g., *Schering Corp. v. Geneva Pharms., Inc., Id.*; *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., Id.*) Thus, Kolterman '220 as evidenced by Tsanev does not provide each and every element of the claimed invention, at least because Kolterman '220 (with or without Tsanev) is silent with respect

to treatment of obesity with amylin or agonists thereof, or the intended population for treatment (i.e., human subject in need of treatment for obesity) of the current claims. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

6. Claims 7, 14 and 16 are not anticpated under 35 U.S.C. § 102(e)(2) over Beaumont as evidenced by Tsanev.

The rejection of Claims 7, 14 and 16 under 35 U.S.C. §102(e)(2), (Final Office Action, page 24, item 34), for alleged anticipation over Beaumont as evidenced by Tsanev, is in error for the reasons of record and the following reasons.

Claims 7, 14 and 16 are not anticipated by the references

Arguments provided above (Rejection 2) regarding the rejection under the non-statutory doctrine of obviousness-type double patenting over Beaumont as evidenced by Tsanev and Rink are hereby reiterated. The claimed invention as exemplified in Claims 7, 14 and 16 is directed to methods of treating obesity in a human subject in need of such treatment through administration of an amylin or an amylin agonist. In contrast, as acknowledged by the Examiner (Final Office Action, page 25, lines 5-8), Beaumont describes "a method of subcutaneous administration to an insulin-requiring human who suffers from Type 1 or Type 2 diabetes mellitus a therapeutically effective amount of an amylin agonist alone such as calcitonin, or calcitonin and insulin, contained in a pharmaceutically acceptable carrier." Beaumont is silent with respect to obesity, treatment of obesity, or intent to treat a human subject in need of treatment for obesity.

In an attempt to cure the deficiency of Beaumont, the Examiner relies on Tsanev to provide alleged evidence that 80-90% of diabetic patients are obese. However, 80-90% falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law. See e.g., *Schering Corp. v. Geneva Pharms., Inc., Id.*; *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., Id.*) Thus, Beaumont patent does not provide each and every element of the claimed invention. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

7. Claims 7, 14, 16 and 17 are not anticipated under 35 U.S.C. § 102(e)(2) over Gaeta as evidenced by Tsanev.

The rejection of Claims 7, 14, 16 and 17 under 35 U.S.C. §102(e)(2), (Final Office

Action, page 27, item 35), for alleged anticipation over Gaeta as evidenced by Tsanev, is in error for reasons of record and the following reasons.

Claims 7, 14, 16 and 17 are not anticipated by the references

Arguments provided above (Rejection 1) regarding the rejection under the non-statutory doctrine of obviousness-type double patenting for Claims 7, 14, 16 and 17 are hereby reiterated. In particular, Gaeta is silent with respect to treating obesity, nothing in Gaeta teaches or suggests the use of an amylin or an amylin agonist in an amount effective to treat obesity, and nothing in Gaeta teaches or suggests the identification of or intent to treat a subject in need of treatment for obesity. In an attempt to cure the deficiency of Gaeta, the Examiner relies on Tsanev (Final Office Action, page 29, lines 27-28) to assert that "every element of the claimed subject matter is disclosed by Gaeta et al. ('411) with the unrecited limitation(s) being inherent as evidence by the state of the art." However, the law is clear that anticipation based on inherency is appropriate only when the prior art relied upon necessarily includes all of the elements of the claims in question (*Atofina v. Great Lakes Chemical Corp.* (*Id.*)) and is the natural result of following the instructions or examples of the prior art. See *SmithKline Beecham Corp. v. Apotex Corp.*, (*Id.*) In the present case, the alleged 80-90% statistic according to Tsanev falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law. Thus, the Gaeta does not anticipate the claimed invention, with or without Tsanev. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

8. Claims 1-7, 11-14, 16 and 17 are not anticipated under 35 U.S.C. § 102(b) over Kolterman 1996 as evidenced by Itasaka.

The rejection of Claims 1-7, 11-14, 16 and 17 under 35 U.S.C. §102(b), (Final Office Action, page 30, item 36), for alleged anticipation by Kolterman 1996 as evidenced by Itasaka, is in error for the reasons of record and the following reasons.

Claims 1-7, 11-14, 16 and 17 are not anticipated by the references

Kolterman 1996 merely describes the use of an amylin agonist, pramlintide, for treating patients with insulin-dependent diabetes mellitus and demonstrates *inter alia* that administration of the amylin agonist significantly reduces postprandial plasma glucose concentrations. However, Kolterman 1996 discloses neither the use of the amylin agonist for treating obesity nor

a reduction in body weight in those patients administered the amylin agonist. Indeed, Kolterman 1996 does not report the weight of the subjects at the end of the study and nothing in the reference indicates that pramlintide had any effect on the weight of the subjects. Accordingly, Kolterman 1996 is silent with regard to the effect of the amylin agonist on body weight.

In an effort to cure the deficiencies of Kolterman 1996, the Examiner relies on Itasaka to allegedly provide a correlation between body mass index (BMI) and obesity. However, nothing in Kolterman 1996 (with or without evidence of Itasaka) suggests that an amylin agonist can be useful in the treatment of obesity, or in the selection of a subject population for such method of treatment. Accordingly, Appellants disagree with the Examiner assertion (Final Office Action, page 31, last line to page 32, line 2) that "the very active step recited in the instantly claimed method was disclosed and practiced by Kolterman et al. in April, 1996." The patient population of Kolterman 1996 is not necessarily the same as the claimed subject, *i.e.*, a subject in need of treatment for obesity. The "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999). Because Kolterman 1996 as evidenced by Itasaka does not teach every element of the claims of the present invention, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Conclusion

The above discussion is fully responsive to all grounds of rejection set forth for the application. In view of the foregoing, it is requested that the Board of Patent Appeals and Interferences remand the application to the Examiner with instructions to remove all rejections and to issue a Notice of Allowance.

The Commissioner is hereby authorized to charge payment for the requisite fees set forth in 37 C.F.R. § 1.136, 37 C.F.R. § 1.17 and/or 37 C.F.R. § 41.20 due for this Appeal Brief to Applicants' Deposit Account No. 010535 referencing Atty. Dkt. No. 226/104 US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

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Respectfully submitted,
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Appendix A: Claims Appendix

1. (Previously presented) A method of treating obesity in a human subject consisting of administering to said subject an amount effective to inhibit weight gain or induce weight loss in said human subject of a composition comprising an amylin or an amylin agonist and a pharmaceutically acceptable carrier, wherein said subject is in need of treatment for obesity.

2. (Previously presented) The method according to claim 1 wherein said amylin agonist is an amylin agonist analogue.

3. (Previously presented) The method according to claim 2 wherein said amylin agonist analogue is ^{25,28,29}Pro-h-amylin (SEQ ID NO:1).

4. (Previously presented) The method according to claim 1 wherein said composition is administered subcutaneously.

5. (Previously presented) The method according to claim 4 wherein said composition is administered from 1 to 4 times per day.

6. (Previously presented) The method according to claim 5 wherein said amylin or amylin agonist contained in said composition is administered in an amount from 30 μg/dose to 300 μg/dose.

7. (Previously presented) A method of treating obesity in a human subject comprising administering to said subject an amount effective to inhibit weight gain or induce weight loss of a composition comprising an obesity relief agent consisting of an amylin or an amylin agonist and a pharmaceutically acceptable carrier, wherein said amount is effective to treat obesity in said

subject, and wherein said subject is in need of treatment for obesity.

9. (Previously presented) The method according to claim 1, 2 or 3 wherein the composition is administered QID and contains said amylin or amylin agonist in an amount of 30 μg/dose.

10. (Previously presented) The method according to claim 1, 2 or 3 wherein the composition is administered TID or QID and contains said amylin or amylin agonist in an amount of 60 μg/dose.

11. (Previously presented) The method according to claim 1, wherein said amylin or amylin agonist contained in said composition is administered in an amount of about 0.01 milligrams per day to about 5 milligrams per day.

12. (Previously presented) The method according to claim 1, wherein said amylin or amylin agonist contained in said composition is administered in an amount of about 0.05 milligrams per day to about 2 milligrams per day.

13. (Previously presented) The method according to claim 1, wherein said amylin or amylin agonist contained in said composition is administered in an amount of about 0.1 milligrams per day to about 1 milligram per day.

14. (Previously presented) A method of treating obesity in a human subject comprising administering to said subject a compound selected from the group consisting of an amylin, an amylin agonist, and salts thereof, wherein said compound is administered in an amount effective to treat obesity in said subject by inhibiting weight gain or inducing weight loss, wherein said subject is in need of treatment for obesity, and wherein said compound is not administered in

conjunction with another obesity relief agent.

15. (Previously presented) The method of claim 1, 2 or 3, wherein the weight of said human subject is reduced after four weeks of said treatment from the weight of said subject prior to said treatment.

16. (Previously presented) A method of treating obesity in a human subject comprising administering to said subject an amount effective to inhibit weight gain or induce weight loss in said subject of a composition consisting essentially of an amylin or an amylin agonist, wherein said amount is effective to treat obesity by inhibiting weight gain or inducing weight loss in said subject, and wherein said subject is in need of treatment for obesity.

17. (Previously presented) The method of claim 7, 14 or 16, wherein said amylin agonist is ^{25,28,29}Pro-h-amylin (SEQ ID NO:1).

Appendix B: Evidence Appendix

None.

Appendix C: Related Proceedings Appendix

None.